Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

July 5, 2002

Dockets Management Branch
5630 Fishers Lane
Room 1061- HFA-305,
Rockville, MD, 20852

RE: **Over-the-counter** Drugs: **Labeling Requirements; Partial. Delay** of **Compliance [Dockets** No. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

To Whom **It May** Concern:

These comments are submitted by the Consumer Healthcare Products Association (CHPA) in response to FDA's April 5,2002, *Federal Register* **publication establishing a partial delay in compliance for certain products which are** subject **to FDA's** final **rule** that **established standardized format and** content **requirements** for **the** labeling **of** all OTC drug **products** (Drug Facts Rule}. **These products** are **designated** in **the** partial **delay** of **compliance as "convenience-size" over-the-counter (OTC)** drug **products.**

CHPA is **the** 121-year-old **trade** organization **representing the manufacturers** and **distributors of nonprescription, or OTC,** medicines and dietary **supplements. CHPA** has **been a principal. industry voice during the evolution of** the Drug Facts Rule, and many **of the** final **provisions of** the rule are similar **to** those **proposed by CHPA. Our association has also discussed with the agency the** matter **of convenience sizes, as noted in the** published partial **delay** in compliance.

CHPA supports FDA's conclusion that "some accommodation **for convenience size packages** is **appropriate,"** and concurs with **the agency's** course of action **to** establish a partial **delay** of **compliance, thereby creating an opportunity for** all **interested parties to** comment **on** the **"viability, desirability, and impact" of a proposed rule for convenience** size OTC drug products. Furthermore, **as part of this process,** CHPA urges **FDA to consider** the broadest range of issues **related to this matter,** both **in the context of the** partial **delay of** compliance as well as in the **questions** the **agency plans to pose** for **public comment** *in* **the** proposed rule.

90P-0201 C81

1150 Connecticut Avenue, N.W. • Washington. D.C.20036-4193 • Tel: 202-429-9260 • Fax: 202-223-6835 • www.chpa-info.org

CHPA Supports FDA's Course of Action to Seek Public Comment.

On May 13,2002, FDA received comments from a third party representing Mechanical Servants, Inc. (MSI) opposing a Citizen Petition submitted by Lil' Drug Store Products, Inc. (LDSP) on May 27, 2001. LDSP's comments were the basis for FDA's publication of a partial delay of compliance. The issues raised by MSI are complicated, requiring due consideration and public comment. Hence, CHPA urges that FDA stay the course it has undertaken and proceed with the development of a public review and comment rulemaking to resolve the various important issues surrounding establishment of a safe harbor for OTC convenience size packages.

FDA Should Cast a Wide Net in Seeking Comments on a Proposed Rule on Convenience Si

The matter of establishing a clear definitional line for OTC convenience sizes is a complicated undertaking, and the potential ramifications of various proposals should be carefully thought out. Therefore, FDA should cast a wide net in seeking comments to its proposed rule. For example:

- Further consideration of the "1 to 2 dose"[1] criterion set forth in the partial delay of compliance needs to be undertaken, and indeed might even be undertaken as part of the delay of compliance in the context of the following rationale. The "1 to 2 dose" rule is inconsistent, and does not fairly treat all OTC products.

  For example under the rule for a solid oral dosage form, a roll of antacids might not be considered a convenience size, yet its use by consumers is typically *prn*, "on-the-go." Convenience and portability *are* key to this product category. An antacid roll typically contains *a* day's dosage (e.g., 3 or 4 tablets per maximum dose, not more than 3 doses per 24 hours). Where the inconsistency in the "1-2 dose" rule comes into play is in the consideration of the antacid example in relation to an oral 12-hour timed release dosage form, where two doses represent a day's treatment. FDA should attempt to bring consistency and fairness to its interim "1-2 dose" rule, and at least consider specific exemptions to its interim rule, both during the delay and in the final resolution of this issue. Other examples might also exist where reasonable exceptions to the "1-2 dose" rule should be considered, and these would undoubtedly be identified in the review and comment period to the proposed rule. For *instance*, consideration should also be given to

[1] FDA's partial delay of compliance for "convenience size" OTC products extends to all OTC drug products that: (1) contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements set for in 201.66(d)(1) to (d)(9) and therefore qualify for labeling modifications currently set forth in 201.66(d)(10). FDA defined "dose" for this purpose as the maximum single serving [i.e., dose] for an adult (or a child for products marketed only for children) as specified in the product's directions for use.

products with no dosage limitations (e.g., sunscreens, antiperspirants, etc.),

- Manufacturers of products which meet the convenience size definition may still elect to follow some of the provisions of the Drug Facts rule to keep a reasonable degree of consistency in the presentation of information across all retail sizes of the same product FDA should seek comments as to how this might be done, including such approaches as utilizing a decreased type size, allowing wrapping of bulleted statements (i.e., a paragraph format) and removing hairlines and bar lines between sections of information, provided the content of the labeling conforms with the appropriate find.monographs. This could be accomplished by FDA making a definitive statement to this effect and waiving compliance action.

- There may be clear opportunities for truncation and abbreviation and possibly deletion of some label elements that would not adversely affect the proper self-selection and subsequent safe and effective use of a particular OTC product. Drawing an inflexible line, as proposed by MSI, that would preclude truncation and abbreviation based on the type of information needed for appropriate self-selection is simply unreasonable. "Other information," toll free numbers, storage conditions, and potentially other information should be considered as suitable areas for truncation, since they would have little bearing on appropriate self-selection.

These are a few of the various issues that FDA should consider in implementing the partial delay of compliance and preparing a proposed rule on OTC convenience sizes. CHPA believes that FDA has taken the right course of action and should proceed to a public review and comment process.

Sincerely yours,

R. William Soller, Ph.D.

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

WS/OTClabeling/Convenience Sizes/ConvSiz Com to Delay[2]

CHPA
FOUNDED 1881

Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Formerly Nonprescription Drug Manufacturers Association

FAX TRANSMISSION

DATE: 7-3-02

TO: DOCKETS MANAGEMENT BRANCH

FROM: DR R WILLIAM SOLLER

NUMBER OF PAGES. 5 (including this cover page)

MESSAGE:

The attached was submitted via e-mail. This is a faxed version.

Please provide confirmation of receipt by fax (202-223-6835) or e-mail (wsoller@chpa-info.org).

If there is a transmission problem, please contact BILL SOLLER at 202-429-9260.

1150 Connecticut Avenue. N.W., Washington. D.C. 20036-4193 Tel: 202-429-9260 Far: 202-223-6835
Web Site: www.chpa-info.org

Soller, Bill

To: fdadockets@oc.fda.gov
Subject: OTC Labeling, Partial Delay of Compliance, Convenience *Sizes:* Dockets 98N-0337; 96N-0420; 95N-0259; 90P-0201

The comments of the Consumer Healthcare Products Association (CHI A) are submitted by attachment to the e-mail **submission** in response to FDA's Federal Register publication perta ning to a partial delay of the compliance **dates** for certain **products subject** *to the* FDA's **final rule that established** standardized format and content **requirements for the** labeling of **over-the-counter** drug **products.**

The **relevant docket** numbers for the rule relating to "Over-the-Counter Human Drugs, **Labeling** Requirements, **Partial** Delay **of Compliance Dates**" are: 98N-0337, 96N-0420, 95N-0259, and 90P-0201.

CHPA's comments are attached.

Please provide a return e-mail to confirm receipt of the attached submission and its entry into the docket

Thank **you,**

R. **William** Soller, Ph.D.
Senior Vice President and
Director of Science & Technology
Consumer **Healthcare** Products Association
1150 Connecticut Ave. NW
Washington, DC 20036
TEL **202-429-3535**
FAX 202-223-6835
wsoller@chpa-info.org

ConvSlz Comm to Delay 2.doc